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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,268	10/10/2003	Felix A. Montero-Julian	BECK1120-1	1728

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EXAMINER	
FOSTER, CHRISTINE E	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,268	MONTERO-JULIAN ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. It is noted that claim 45 recites a method according to "claim 27 or 21," yet claim 21 is directed to a system (product) and not to a method. For the purposes of restriction claim 45 was assumed to depend from claim 27 or **claim 32** as in claims 44 and 46.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19 and 23-26 (in part), drawn to a system and kit comprising an **MHC class I monomer or modified MHC class I monomer**, classified in class 530, subclass 387.9 and in class 422, subclass 61, respectively.

II. Claims 1, 3-10, 13-14, and 20-26 (in part), drawn to a system and kit comprising an **MHC class II monomer or modified MHC class II monomer**, classified in class 530, subclass 387.1 and in class 422, subclass 61, respectively.

III. Claims 27-31, 38-54, 57-62, and 64-67 (in part), drawn to methods for determining binding between a **MHC class I monomer or modified MHC class I monomer** and a putative MHC-binding peptide therefor, classified in class 436, subclass 518.

IV. Claims 32-46 and 55-67 (in part), drawn to methods for determining binding between a **MHC class II monomer or modified MHC class II monomer** and a putative MHC-binding peptide therefor, classified in class 436, subclass 501.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially

different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because MHC class I and MHC class II molecules have different protein subunit structures and serve distinct functions in antigen presentation. For example, MHC class I is composed of beta-2-microglobulin (as in claims 15 and 18), while MHC class II does not contain this subunit. In addition, the two classes of MHC molecules have different binding specificities, binding different types of peptides from different sources, and activate different subsets of T cells. As a result of these structural and functional differences, the claimed systems do not overlap in scope, and furthermore would require different anti-MHC antibodies and different MHC-binding peptides, since antibodies and peptides that bind to one MHC class would not bind to the other. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions (I and III) and (II and IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the systems and kits of Groups I-II may be used either in the methods of determining binding of Groups III-IV or in the method of determining degree of binding affinity of Groups V-VI, or in a distinct method, for example a method of purifying MHC-binding peptides from combinatorial peptide libraries.

5. Inventions III and IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed do not overlap in scope because as discussed above with respect to Groups I and II, class I and class II MHC molecules differ with respect to structure, function, and peptide binding specificity. As such, the methods of Groups III and IV would require different peptide and antibody reagents in order to carry out the claimed methods of determining binding, since a peptide that binds to MHC class I would not be recognized by MHC class II, for example. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Inventions (I and IV) and (II and III) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and differ with respect to design, ingredients, modes of operation, and effects. The system and kit of Group I, comprising MHC class I monomer, are neither made by nor used in the methods of determining binding/binding affinity between a MHC class II monomers and a putative MHC-binding peptide as in Group IV. Similarly, the system and kit of Group II, comprising MHC class II monomer, are neither made by nor used in the method of determining binding/binding affinity between MHC class I monomers and a putative MHC-binding peptide as in Group III.

These inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification. Moreover, the searches required for one group are not required for the others. In addition to the classification-based search of the patent literature, text searches of the non-patent literature would also be non-coextensive due to the different limitations recited in each group. Therefore, restriction for examination purposes as indicated is proper.

Election of Species

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a. **Type of MHC** (elect one of the following):

i. HLA subclass A (see claims 31 and 53)

ii. HLA subclass B (see claims 31 and 53)

iii. HLA subclass C (see claims 31 and 53)

iv. HLA subclass D (see claims 37 and 63)

v. HLA subclass DR (see claims 37 and 63)

vi. HLA subclass DP (see claims 37 and 63)

vii. HLA subclass D (see claims 37 and 63)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. **The reply must also**

identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The claims are deemed to correspond to the species listed above in the following manner:

With respect to Group I, claims 1-19 and 23-26 appear to be generic.
With respect to Group II, claims 1, 3-10, 13-14, and 20-26 appear to be generic.
With respect to Group III, claims 27-30, 38-52, 54, 57-62, and 64-67 appear to be generic. Claims 31 and 53 are subject to species election.
With respect to Group IV, claims 32-36, 38-46, 55-62, and 64-67 appear to be generic. Claims 37 and 63 are subject to species election.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species of MHC molecules represents a different molecule with a unique polypeptide sequence that is encoded by a different gene. Each species differs with respect to specificity of peptide binding and serve different function. Moreover, a search of all of the various subclasses would require non-coextensive searches of the patent and non-patent literature. As such, it would be burdensome to search all of the species.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.
10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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